Contents: Nonconformances, Identifying and Reporting

Effective Date: **December 2003**
Point of Contact: Quality Programs & Services Office

Section	Overview of Content (see section for full process)
Introduction	
1. Identifying, Classifying, and Reporting a Nonconformance	• Notify responsible individual of a potential nonconformance. • Evaluate the potential or actual nonconformance and process according to an applicable SBMS procedure (if any) or a Nonconformance Report (NCR) Form. • Use the graded approach in dispositioning, documenting, and reporting nonconformances.
Definitions	

Exhibits
Nonconformances, Identifying and Reporting Flowchart
SBMS Procedures by Types of Nonconformances

Forms
Nonconformance Report (NCR) Form

Training Requirements and Reporting Obligations

This subject area does not contain training requirements.

This subject area does not contain reporting obligations.

References

Accelerator Safety Subject Area

Assessment Tracking System (ATS)

BNL Supplier Nonconformance (BSNC) Reporting and Tracking System, Procurement & Property Management web site (*Limited Access)

Construction Safety Subject Area

Corrective and Preventive Action Subject Area

Critiques Subject Area

Environment, Safety, Health and Quality (Tier I) Inspections Subject Area

Environmental Assessments Subject Area

ES&H Standard 1.11.0, Aviation Safety

ES&H Standard 1.1.1, Price-Anderson Amendments Act Compliance Validation and Noncompliance Reporting Program

ES&H Standard 1.2.1, Corrective Action Management and Tracking for Internal and External Assessments

ES&H Standard 1.3.2, Operational Readiness Review

ES&H Standard 1.9.0, Traffic Safety

Graded Approach for Quality Requirements Subject Area

Inspections and Acceptance Subject Area

Integrated Assessment Program Management System Description

Internal Controlled Documents Subject Area

Investigation of Incidents, Accidents, and Injuries Subject Area

Lifting Safety Subject Area

Maintenance Management Subject Area

Occurrence Reporting and Processing System (ORPS) Subject Area

Price-Anderson Amendments (PAAA) Act web site

Published Lessons Learned web site

Radiological Awareness Reports Subject Area

Radiological Awareness Reports Subject Area

Radiological Stop Work Procedure

Software Quality Assurance Subject Area

SPI 3-03, Materials and Property Management

SPI 5-05, Government Vehicles

Spill Response Subject Area

SSM 11.0, Ethics in the Conduct of Research

Stop Work - Imminent Danger Procedure

Suspect/Counterfeit Items Subject Area

Work Planning and Control for Experiments and Operations Subject Area

*Access Limited to BNL Staff and Authorized non-BNL Staff

Standards of Performance

All staff and guests shall promptly report accidents, injuries, ES&H deficiencies, emergencies, and off-normal events in accordance with procedures.

Managers shall respond promptly to staff concerns and take appropriate corrective actions.

All scientific and professional staff shall identify and control items and material affecting scientific results.

Management System

This subject area belongs to the **Quality Management** management system.

Back to Top

3.4-082004/standard/07/0700t011.htm

Introduction: Nonconformances, Identifying and Reporting

Effective Date: **December 2003**
Point of Contact: Quality Representative

This subject area provides a consistent approach to handling (identifying and reporting) nonconformances. It addresses the use of other Standards-Based Management System (SBMS) procedures for identifying and resolving nonconforming conditions and provides a methodology for handling nonconformances when other SBMS procedures do not apply. It was designed to contribute to an organization's continuous improvement culture and supports other Laboratory initiatives, e.g., the Lessons Learned Program and Integrated Assessment Program.

Nonconformances are situations where the quality and usability of items, services, activities, or processes do not meet requirements. Nonconformances must be identified, controlled, and corrected using a graded approach. See the Graded Approach for Quality Requirements Subject Area.

- Nonconformances determined to have an ESH&Q Risk Level of High (A1- Critical) or Moderate (A2 - Major) must be formally documented, dispositioned, and closed out, in accordance with the requirements of this subject area.
- Nonconformances determined to have an ESH&Q Risk Level of Low (A3 - Minor) are dispositioned and documented, as appropriate.
- Nonconformances determined to have an ESH&Q Risk Level of Negligible (A4 - Negligible), are dispositioned, as appropriate. Documentation is not required.

The graded approach ensures that the processing of the nonconformance is commensurate with the actual/potential impact of the nonconformance. However, the graded approach does not allow internal or external requirements to be ignored or waived.

Several procedures are available within SBMS for handling nonconformances. This subject area provides a roadmap of the appropriate procedure to be used. When required, corrective and preventative actions are to be taken in accordance with the Corrective and Preventive Action Subject Area.

- All nonconformances from abnormal conditions/events must be considered for the Occurrence Reporting and Processing System (ORPS) Subject Area. For those that fall below the ORPS reporting threshold, this subject area is followed.
If the nonconformance is the result of an assessment, inspection/test, or is addressed

- If the nonconformance is the result of an assessment, inspection/test, or is addressed via a maintenance program, then the nonconformance is processed according to the applicable SBMS procedure, and this subject area is not followed.
- If the nonconformance is the result of an accident or incident, then the nonconformance is processed according to the applicable SBMS procedure, for example, the Radiological Awareness Reports Subject Area, and this subject area is not followed.

If the nonconformance is not addressed by another SBMS procedure, then this subject area is followed.

Back to Top

3.0-122003/standard/07/0700i011.htm

Subject Area: ***Nonconformances, Identifying and Reporting***

1. Identifying, Classifying, and Reporting a Nonconformance

Effective Date: **December 2003**
Point of Contact: Quality Representative

Applicability

This information applies to BNL staff and non-BNL staff who identify a potential or actual nonconforming item, service, activity, or process.

Required Procedure

Staff must report conditions or activities that they perceive may represent a nonconformance to the organization responsible for the item, service, activity, or process. When necessary and appropriate (based on a graded approach), staff take action to mitigate potential ES&H or quality/programmatic impacts of the nonconforming condition. This can be done in several ways, including

- issuing a formal stop work in accordance with the Radiological Stop Work Procedure or the Stop Work - Imminent Danger Procedure, when appropriate;
- reporting a purchased item or service that is nonconforming to the Procurement and Property Management (PPM) Division;
- tagging and segregating a nonconforming item; or
- issuing immediate notification to the responsible individual when a nonconforming item, service, activity, or process is observed.

A designated individual from the responsible organization (responsible individual) evaluates the potential or actual nonconformance and takes the appropriate action in accordance with this procedure. Refer to the Nonconformances, Identifying and Reporting Flowchart for an overview of this procedure.

Identifying, Classifying, and Reporting a Nonconformance contains three subsections.

1.3 Documenting and Reporting a Nonconformance

1.1 Identifying a Nonconformance

Step 1	Identify a situation through observation or inquiry in which requirements may not have been met for an item, service, activity, or process.
Step 2	Notify the responsible individual or designee that a potential or actual nonconformance exists.
Step 3	The responsible individual or designee determines if a nonconformance has occurred (see the Guidelines section below for assistance in making this determination or contact a Quality Representative). • If the responsible individual or designee determines that a nonconformance *has* occurred, they prevent the inadvertent use of the item, service, activity, or process, as applicable. • If the responsible individual or designee determines that a nonconformance *has not* occurred, they decide whether or not to document the decision. No further action is required by this subject area. **Note:** If the person who identified the situation does not concur with the decision, they may report the situation to the immediate supervisor, Office Manager, Department Chair/Division Manager, or Assistant Laboratory Director.

1.2 Classifying a Nonconformance

Step 1	All nonconformances must be considered for the Occurrence Reporting and Processing System (ORPS) Subject Area. If the nonconformance is ORPS reportable, then proceed to the Occurrence Reporting and Processing System (ORPS) Subject Area. If the nonconformance is not ORPS reportable, refer to the exhibit SBMS Procedures by Types of Nonconformances to see if it is addressed by an existing process or SBMS procedure. If the nonconformance is addressed by a procedure or process listed in the exhibit or by an approved documented procedure or process, proceed in accordance with that procedure or process. No further action is required by this subject area. If the nonconformance is not addressed by an existing procedure or process, then proceed to step 2.
Step 2	The ESH&Q Risk Level must be determined from either the preassigned Risk Level of the item/process or from the impact of the nonconformance on the process or system. To determine the impact of the nonconformance, refer to the Screening Guidelines for Work Planning & Control and Application of the Quality Graded

	Approach in the Work Planning and Control for Experiments and Operations Subject Area. With the exception of supplier-related nonconformances, initiate documentation of the nonconformance on the Nonconformance Report (NCR) Form, or equivalent, if the nonconformance is determined to have an ESH&Q Risk Level of High (A1- Critical) or Moderate (A2 - Major), and proceed to step 1 in subsection 1.3 Documenting and Reporting the Nonconformance. If the nonconformance is determined to have an ESH&Q Risk Level of Low (A3 - Minor), then disposition the nonconformance and document, as appropriate, for use in trend analysis and improving performance towards goals and objectives. No further action is required by this subject area. If the nonconformance is determined to have an ESH&Q Risk Level of Negligible (A4 - Negligible), then disposition the nonconformance, as appropriate. Documentation is not required. No further action is required by this subject area. **Note:** Regardless of the Risk Level, all nonconformances of purchased items or services that are supplier-related are reported using the BNL Supplier Nonconformance (BSNC) Reporting and Tracking System.

1.3 Documenting and Reporting a Nonconformance

Step 1	The responsible individual or designee forwards a copy of the initial nonconformance report or equivalent to the Quality Programs & Services Office. For nonconformance of purchased items or services, the Procurement and Property Management (PPM) Division is automatically notified, via e-mail, through the BNL Supplier Nonconformance (BSNC) Reporting and Tracking System. **Note:** The Quality Programs & Services Office evaluates the report for contribution toward BNL systems, such as Published Lessons Learned, tracking and trending, and programmatic Price-Anderson Amendments Act (PAAA) issues. **Note:** The Quality Programs & Services Office ensures that the BNL Price-Anderson Amendments Act (PAAA) Coordinator receives the applicable NCR within ten days of receipt.
Step 2	Proceed to the Corrective and Preventive Action Subject Area to analyze the nonconformance and determine what corrective and preventive actions are to be taken.
Step 3	Perform the independent verification, if required. Finalize the Nonconformance Report (NCR) Form, or equivalent, and distribute it to the appropriate individuals, including the Quality Programs & Services Office.

Guidelines

General

- Each nonconformance should be reported on a separate form. Closing out the nonconformance can be delayed if multiple nonconformances requiring multiple corrective actions are tied to one nonconformance reporting document.
- When a disposition of rework, scrap, or repair of purchased items is made, the Procurement and Property Management (PPM) Division should be consulted to determine whether the BNL costs in carrying out the disposition can be charged back to the supplier. If the item is from a BNL organization, they should be consulted to determine if there is any charge back.
- For nonconformances concerning purchased items or services, a Supplier Corrective Action Request should be made if warranted by the nature of the nonconformance and past history. Refer to the Supplier Corrective Action Request (SCAR) Form in the Corrective and Preventive Action Subject Area.

In determining if a nonconformance has occurred, consider doing the following:

- collect information, review conditions, circumstances, pertinent trends, or previous instances of the situation;
- identify and review standards, requirements, and regulatory drivers;
- involve the appropriate Subject Matter Experts;
- determine what (if any) other items, services, activities, or processes were affected by the situation.

For example,

- If there was a failure to comply with radiological postings or Radiological Work Permit (RWP) requirements, follow the Radiological Awareness Reports Subject Area.
- When a review/assessment identifies that experimental activities involving radiological issues are found to be outside the approved experimental operating envelope of an existing experiment, follow the Work Planning and Control for Experiments and Operations Subject Area.
- For assessments of completed Work Permits, follow the Work Planning and Control for Experiments and Operations Subject Area.

As applicable, consider reporting the following nonconformances:

- nonconformance of BNL stock items to the Procurement and Property Management (PPM) Division;
- nonconformance of items provided by the BNL organization to that organization;
- unresolved nonconformances for credit card purchases to the Credit Card Administrator in PPM.

References

BNL Supplier Nonconformance (BSNC) Reporting and Tracking System, Procurement &

Property Management web site (*Limited Access)

Corrective and Preventive Action Subject Area

Occurrence Reporting and Processing System (ORPS) Subject Area

Price-Anderson Amendments Act (PAAA) web site

Published Lessons Learned, Standards-Based Management System web site

Radiological Awareness Reports Subject Area

Radiological Stop Work Procedure

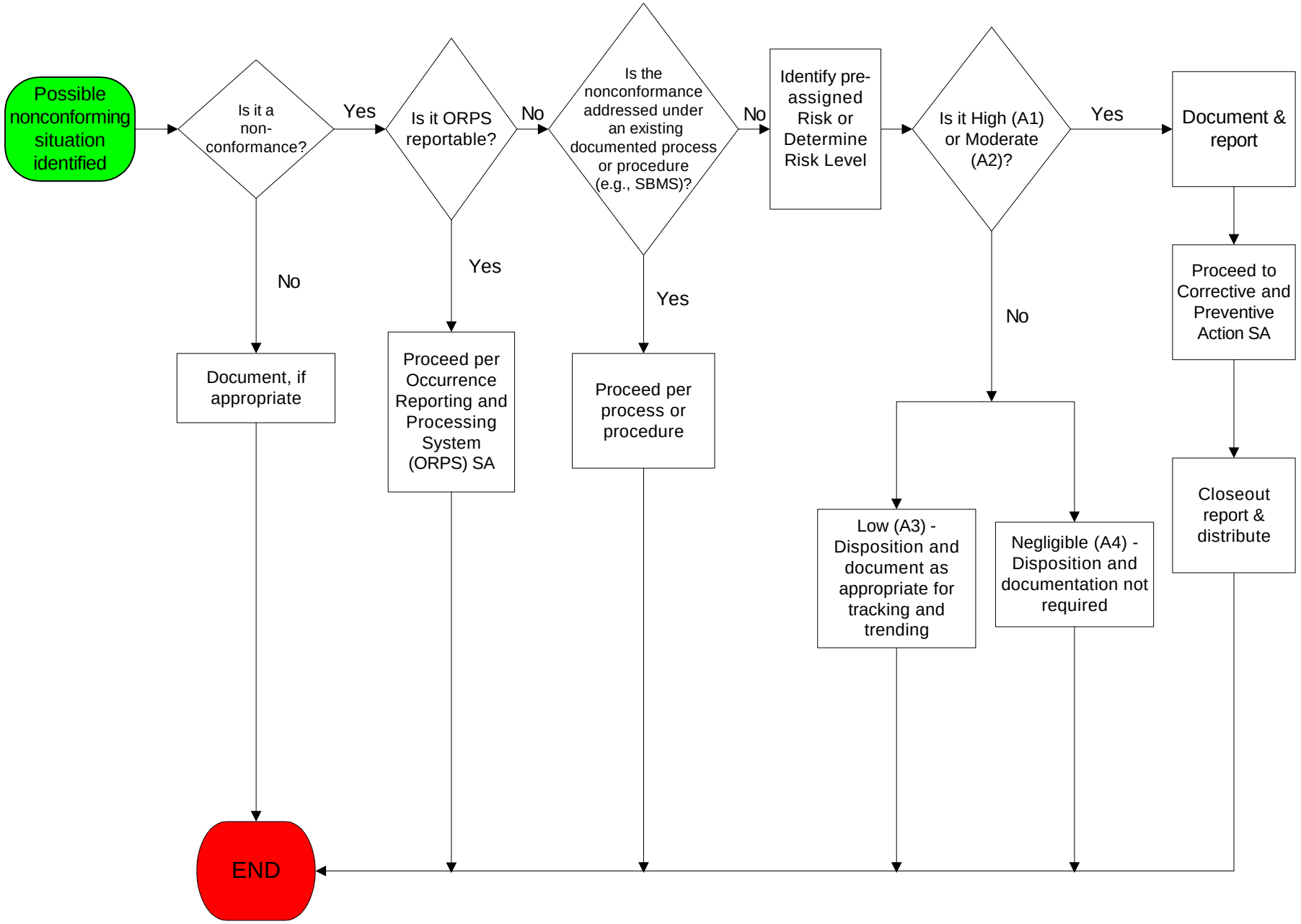
Stop Work - Imminent Danger Procedure

Work Planning and Control for Experiments and Operations Subject Area

Back to Top

1.0-122003/standard/07/0701d011.htm

Nonconformances, Identifying and Reporting Flowchart



Subject Area: ***Nonconformances, Identifying and Reporting***

SBMS Procedures by Types of Nonconformances

Effective Date: **June 2000**
Point of Contact: Quality Representative

If you use other procedures which are not listed here, contact a Quality Representative, who will ensure that they are incorporated into these tables.

Table 1

Type of Nonconformance	SBMS Procedure
Assessment findings	BNL-O&M-I-02 Conduct of Operations, Conformance Self-Assessment ES&H Standard 1.2.1, Corrective Action Management and Tracking for Internal and External Assessments ES&H Standard 1.3.2, Operational Readiness Review Accelerator Safety Subject Area Construction Safety Subject Area Critiques Subject Area Environment, Safety, Health and Quality (Tier I) Inspections Subject Area Environmental Assessments Subject Area Integrated Assessment Program Management System Description Lifting Safety Subject Area

	Work Planning and Control for Experiments and Operations Subject Area
Inspection/Test	Inspections and Acceptance Subject Area Software Quality Assurance Subject Area Supplier Nonconformance Reporting and Tracking System Suspect/Counterfeit ItemsSubject Area
Maintenance	Maintenance Management Subject Area

Table 2

Type of Nonconformance	SBMS Procedure
Incidents or Accidents	ES&H Standard 1.9.0, Traffic Safety ES&H Standard 1.11.0, Aviation Safety Investigation of Incidents, Accidents, and Injuries Subject Area Radiological Awareness Reports Subject Area Scientific Staff Manual (SSM) 11.0, Ethics in the Conduct of Research Spill Response Subject Area Standard Practice Instruction (SPI) 3-03, Materials and Property Management Standard Practice Instruction (SPI) 5-05, Government Vehicles

Back to Top

3.4-082004/standard/07/0703e011.htm

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Subject Area: ***Nonconformances, Identifying and Reporting***

Nonconformance Report (NCR) Form

Effective Date: **December 2003**
Point of Contact: Quality Representative

The instructions for completing the Nonconformance Report (NCR) Form are given below. These instructions can also be used to develop an equivalent form or process. An equivalent form or process must address the following contents; however, they are not required to be labeled with these specific headings, nor are they required to be incorporated into one form or process.

The Nonconformance Report (NCR) Form is provided as a Word file.

Block	To be completed by staff on the Nonconformance Report Form
Identification	
Originator	Individual who identified the nonconformance.
Organization	The department, division, or group that is responsible for the nonconformance.
Date	Date the nonconformance was identified.
Report Number	Enter a unique report number to be used for identification and tracking.
Nonconformance Description	Describe the nonconformance; ensure the applicable requirements, planned activities, procedures, specifications, drawing, standards, serial numbers are noted. Indicate who documented the nonconformance. Consider the following for use in the description: • ES&H and Programmatic Impact • ILR/Purchase Order (P.O.) Number • Part Name • Part Number and Revision

	• Quantity • Apparent Cause
Steps to Prevent Inadvertent Use of the Item or Process	Describe how the item or process was identified and separated from other items. Indicate any actions taken to mitigate any environment, safety, and health impacts, if applicable.
Corrective/Preventive Action and Disposition	
Planned Corrective/Preventive Action	Describe for each cause what action(s) will be taken with the item or process, including as applicable, the completion dates, disposition of material, and responsible staff for each action. Describe, as applicable, what actions are needed to prevent recurrence of the identified nonconformance, such as process improvement, procedure revisions, training plan, and include completion dates and responsible staff for each action. Indicate who approved the Corrective/Preventive Action and date. **Note:** Consider whether Independent Verification is necessary.
Independent verification required? Yes ___ No___	Indicate if independent verification is required.
Disposition	Note the decided action taken on the item/service.
Person(s) Responsible for the Corrective/Preventive Action and Disposition	Name of the person(s) responsible for completing the corrective/preventive action and disposition.
Approval of Corrective/Preventive Action and Disposition	Person authorized to approve the actions and disposition, and the date of approval.
Closing the Nonconformance	
Action has been Completed	Person authorized to approve completion of the actions, and the date of completion.
Independent Verification has been Completed	Indicate who performed the verification and date, if applicable (this cannot be the person doing the work).
Distribution	Distribute working copies of the nonconformance report (and other appropriate documents) that defines the corrective and preventive actions to appropriate individuals. (Distribute an initial and final copy to the Quality Programs & Services Office.)

Back to Top

3.3-072004/standard/07/0701e011.htm

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NONCONFORMANCE REPORT (NCR)

Identification

Originator	Organization	Date	Report Number

Nonconformance Description (Describe the nonconformance; ensure the applicable requirements, planned activities, procedures, specifications, drawing, standards, serial numbers, etc. are noted. Indicate who documented the nonconformance. Consider the following for use in the description: ILR/Purchase Order (P.O.) Number, Part Name, Part Number and revision, Quantity, and Apparent Cause.)

ESH&Q Risk Level

Steps to Prevent Inadvertent Use of the Item or Process

Corrective/Preventive Action and Disposition

Planned Corrective/Preventive Action (Describe for each cause what action(s) will be taken with the item or process, including, as applicable, the completion dates, disposition of material, and responsible staff for each action. Describe, as applicable, what actions are needed to prevent recurrence of the identified nonconformance, such as process improvement, procedure revisions, training plan, etc., and include completion dates and responsible staff for each action.)

Independent verification required? Yes ☐ **No** ☐

Disposition **Note:** For Suspect/Counterfeit Items (S/CI), do not use the disposition options below. Follow the Suspect/Counterfeit Items Subject Area to determine disposition.

Use-as-is ☐ Repair ☐ Rework ☐ Return To Vendor ☐ Scrap ☐ Other

Person(s) Responsible for the Corrective/Preventive Action and Disposition	Approval of Corrective/Preventive Action and Disposition
_____	_____
Name *Date*	*Name* *Date*

Closing the Nonconformance

Action Completed	Independent Verification Completed (if required)
_____	_____
Name *Date*	*Name* *Date*

Distribution:

Quality Management Office Initial ☐ Final ☐ (Note: For ESH&Q Risk Level A-1/A-2 only)

Definitions: Nonconformance and Corrective and Preventive Action

Effective Date: **June 2000**

Point of Contact: Quality Representative

Term	Definition
activity	A project, program, study, or experiment which can involve the construction or assembly, operation, monitoring, and maintenance of research apparatus and equipment. The activity may also be a combination of the two, i.e., designing and building the research apparatus and equipment, and then conducting research with it.
cause	A condition or event that results in an effect (anything that shapes or influences the outcome). This may be anything from noise in an instrument channel, a pipe break, an operator error, or a weakness or deficiency in management or administration.
corrective action	A purposeful change implemented to eliminate a specific cause of an identified nonconformance.
disposition	A decision to determine the ultimate resolution of a nonconforming item/activity, such as scrap, rework, use-as-is, repair, or return to vendor.
independent verification	An assurance, by an individual that was not responsible for the corrective/preventive actions, that the actions were completed properly.
item	An all-inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, unit, or support systems.
nonconformance	A deficiency in a characteristic, documentation, or procedure that renders the quality of an item or service unacceptable or questionable. Examples of nonconformances include physical defects, test failures, incorrect or inadequate documentation of data, or deviation from prescribed processing, inspection, or test procedures, including the following: • a failure to follow established procedures • a failure to develop, document, or implement any required element of a program (i.e., Quality Assurance, Conduct of Operations, Maintenance or Environmental Management System) or activity established by mutual agreement with the client • a situation in which the quality of an activity or document is questionable (e.g., where the stated or implied purpose has not been met or where insufficient information exists to support the results that have been produced) • not adhering to legal or other requirements, including administrative ones, such as labeling, records, or other documentation requirements

preventive action	A purposeful change implemented to avoid potential nonconformances.
Quality Representative (QR)	The technical representative assigned to coordinate, assist, and monitor the implementation of quality assurance activities within a department/division.
repair	The restoration of an item to an acceptable nonconforming condition through approved repair procedures (e.g., welding, plugging, inserts, or splicing).
responsible individual	The individual within a department or division responsible for evaluating and processing the nonconformance.
rework	The completion or correction of an item to a conforming condition by processing the material through conventional operations that are part of the normal manufacturing process.
root cause	The underlying cause of an adverse condition, which when corrected, will prevent recurrence of that condition.
scrap	Whenever the items are unfit for use and repair, determined to be uneconomical, or are designated by the cognizant manager to be scrap.
use-as-is	The acceptable use of an item while exhibiting a nonconformance.

Back to Top

2.0-062000/standard/07/0700l011.htm

Revision History: Nonconformances, Identifying and Reporting

Point of Contact: Quality Programs & Services Office

Revision History of this Subject Area

Date	Description	Management System
August 2004 -- Minor Rev. 3.4	The Environment, Safety, Health and Quality (Tier I) Inspections Subject Area replaces ES&H Standard 1.2.0, Departmental Environment, Safety & Health Inspections.	Quality Management
July 2004 -- Minor Rev. 3.3	Construction Safety Subject Area replaces ES&H Standard 1.3.1, Construction Safety.	Quality Management

December 2003	The subject area was revised to reflect the following changes:
	• The sections Identifying a Potential Nonconformance and Closing the Nonconformance were combined into one section Identifying, Classifying, and Reporting a Nonconformance, which contains three subsections:
	  ○ 1.1 Identifying a Nonconformance
	  ○ 1.2 Classifying a Nonconformance
	  ○ 1.3 Documenting and Reporting a Nonconformance
	• The section Analyzing the Nonconformance and Determining
		Quality Management

	Corrective and Preventive Action was removed and rewritten as part of the new Corrective and Preventive Action Subject Area. A link to the subject area has been added in subsection 1.3. • The reporting process of supplier-related nonconformances was clarified in subsection 1.2.	
June 2000	This subject area was revised to describe the use of the graded approach in reporting, dispositioning, and closing-out of nonconformances. Nonconformances must be identified, controlled, and corrected using a graded approach. • Nonconformances determined to have an ESH&Q Risk Level of High (A1- Critical) or Moderate (A2 - Major) must be formally documented, dispositioned, and closed out, in accord with the requirements of this subject area. • Nonconformances determined to have an ESH&Q Risk Level of Low (A3 - Minor) are dispositioned, and documented, as appropriate. • Nonconformances determined to have an ESH&Q Risk Level of Negligible (A4 - Negligible), are dispositioned, as appropriate. Documentation is not required. Several SBMS procedures are available for handling nonconformances. This subject area provides a roadmap of them.	Quality Management
March 1999	This information was developed by a team using the process for Standards-Based Management System development. This subject area is a replacement for BNL-QAG-801, "Nonconformance Reporting and Corrective Action." BNL Quality	Quality Management

	and Corrective Action," BNL Quality Assurance Manual.	

Back to Top

3.4-082004/standard/07/0700a011.htm

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